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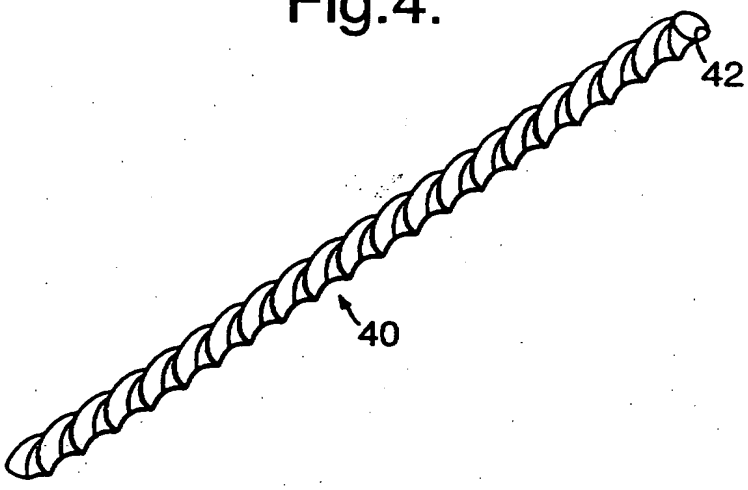
(54) Vascular graft

(57) A vascular graft comprises a tubular vessel having a lumen. In cross-section, the lumen has a periphery which is non-circular and the orientation of the non-circular periphery rotates as a function of position along the length of the graft in order to impart rotational flow velocity components to a fluid passing along the graft to thereby alleviate the problem of stenosis, particularly at an end-to-side anastomosis.

Fig.4.



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significantly flattened which reduces the cross-sectional area and increases the perimeter of the lumen which reduces the patency of the graft and increases viscous flow losses to the graft which increase the pressure drop along the length of the graft which is undesirable.

[0015] Preferably the rotational flow velocity imparting portion of the graft is at the out-flow end of the graft. This enables the in-flow or proximal end of the graft to be a simple conduit for predominantly axial flow for greater throughput whilst the rotational flow is induced at the outflow end where the most profound turbulence and stenosis problems have previously occurred.

[0016] Alternatively the rotational flow velocity imparting feature of the graft can extend along substantially its entire length which is simpler to manufacture.

[0017] Preferably the maximum imparted rotational flow velocity component is at least 5% and more preferably at least 20% of the mean axial velocity in order to stabilise the flow and alleviate the above mentioned problems.

[0018] The invention also provides the method of making a graft as defined in the above aspects of the invention, by the step of extruding a surgically acceptable material through a die whilst rotating the die to form the lumen of non-circular periphery which rotates along the length of at least a portion of the graft.

[0019] The invention also provides another method of making a graft as defined in the above aspects of the invention, comprising the steps of: providing a mandrel, whose exterior surface corresponds to the desired interior surface of the graft or portion of the graft; coating the mandrel with a surgically acceptable material; and unscrewing the mandrel to leave the graft or portion thereof.

[0020] Thus simple methods of manufacturing this advantageous graft are provided.

[0021] The invention also provides a method of treatment and a use of the graft of the invention by implanting the graft in a patient, such as a human.

[0022] Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 is a schematic cross-sectional view of stenosis at an end-to-side anastomosis;

Figs. 2(a), (b) and (c) illustrate a portion of a graft according to one embodiment of the invention; (a) shows a sequence of transverse cross-sections of the graft; (b) is an end-on view of a transverse cross-section of the graft; and (c) is a perspective view of the graft;

Figs. 3(a) and (b) are plots of the in-plane (rotational) flow velocity components in transverse cross-sections of grafts according to two further embodiments of the invention;

Fig. 4 is a perspective view of a portion of graft according to another embodiment of the invention; and

Fig. 5 is a plot of the in-plane (rotational) flow velocity components in a transverse cross-section of the graft according to the embodiment of Fig. 4.

[0023] A first embodiment of the invention will be described with reference to Fig. 2. Fig. 2(c) shows a portion of a graft 20 which basically comprises a cylindrical tube having a lumen 22. The graft 20 in this and subsequent embodiments may be an artificial vessel, for example, made of PTFE or other synthetic material, such as polyesters (e.g. Dacron ™), polyurethanes (e.g. ester and carbonate urethanes) and silicones. Fig. 2(a) shows a series of successive transverse cross-sections 24 through the graft 20, only the first one has been labelled 24 and is shown end on in Figure 2(b). The lumen 22 has a periphery 26 which in this example is predominantly circular, but there is an intraluminal protrusion 28 such that overall the periphery of the lumen in transverse cross-section is non-circular. In this embodiment, as shown in Figure 2(b), the height H and the width D of the protrusion 28 are approximately equal to each other and the height H is about one eighth of the internal diameter of the lumen 22. The grafts of this and the following embodiments of the invention typically have a diameter in the range of 5 to 8 mm.

[0024] As can be seen in Figure 2(a), the position of the protrusion 28 rotates as a function of position along the length of the graft about an axis parallel to the length of the graft. The locus of the protrusion 28 is indicated by the dashed line 30 in Figure 2(c). Overall the protrusion takes the form of a helicoidal rib in the lumen 22 of the graft 20. The rib has a spatial period L as shown in Figure 2(a).

[0025] Two further embodiments of the graft of the invention with intraluminal projections are illustrated with reference to Figures 3(a) and 3(b). Each of these figures shows the lumen of the graft taken at a transverse cross-section. As can be seen, the periphery of each lumen is basically circular, but with three intraluminal projections circumferentially spaced at equal angles such that overall the periphery of the lumen is non-circular. Each of the intraluminal protrusions is in the form of a helicoidal rib as described with reference to Figure 2. In the two specific examples of Figures 3(a) and 3(b), the full internal diameter of the lumen is approximately 6 mm and each of the ribs is about one third of a millimetre wide at its base where it joins the inner wall of the graft from which it projects radially inwards.

[0026] The difference between the grafts of Figures 3 (a) and 3(b) is that in Figure 3(a) the intraluminal protrusions are approximately one quarter of the diameter of the lumen, whereas in Figure 3(b) each protrusion is approximately one tenth of the diameter.

[0027] Figures 3(a) and 3(b) illustrate the in-plane flu-

6. A graft according to any one of claims 2 to 5, wherein the maximum height of the or each protrusion is at least 0.5 mm.

7. A graft according to any one of claims 2 to 6, wherein the maximum height of the or each protrusion is at least one tenth of the diameter of the lumen.

8. A graft according to claim 7, wherein the maximum height of the or each protrusion is at least one quarter of the diameter of the lumen.

9. A graft according to any one of claims 2 to 8, comprising a plurality of said intraluminal protrusions spaced at substantially equal angles around the periphery of said lumen.

10. A graft according to any one of the preceding claims, wherein said periphery of said lumen is substantially elliptical, oval or flattened-circular.

11. A graft according to claim 10, wherein the ratio of the major diameter to the minor diameter of said periphery is in the range of from approximately 3:1 to 4:3, preferably approximately 3:2.

12. A graft according to any one of the preceding claims, wherein said portion of said lumen is at the out-flow end of said graft.

13. A graft according to any one of claims 1 to 11, wherein said portion of said lumen comprises substantially the entire length of said graft.

14. A graft according to any one of the preceding claims for imparting significant rotational velocity flow components to a fluid passing along said graft.

15. A graft according to claim 14, wherein the maximum imparted rotational flow velocity component is at least 5% of the mean axial velocity.

16. A graft according to claim 15, wherein the maximum imparted rotational flow velocity component is at least 20% of the mean axial velocity.

17. A graft according to any one of the preceding claims, wherein the period of rotation of the non-circular periphery is in the range of from approximately 3 to 10 times the diameter of the lumen.

18. A method of making a graft defined in any one of the preceding claims, comprising the step of extruding a surgically acceptable material through a die whilst rotating the die to form said lumen of non-circular periphery which rotates along the length of at least a portion of said graft.

19. A method of making a graft defined in any one of claims 1 to 17, comprising the steps of: providing a mandrel, whose exterior surface corresponds to the desired interior surface of the graft or portion of the graft; coating the mandrel with a surgically acceptable material; and unscrewing the mandrel to leave the graft or portion thereof.

20. Use of a graft according to any one claims 1 to 17 in the human vasculature.

21. A method of treatment comprising the step of implanting a vascular graft according to any one of claims 1 to 17 in a patient.

22. A method of alleviating stenosis in a living vessel as a result of joining a vascular graft to said vessel, said method comprising the step of implanting said graft wherein said graft comprises at least a portion for imparting rotational flow velocity components to a fluid passing along said graft.

23. A method according to claim 22 wherein said living vessel is a blood vessel and said fluid is blood.

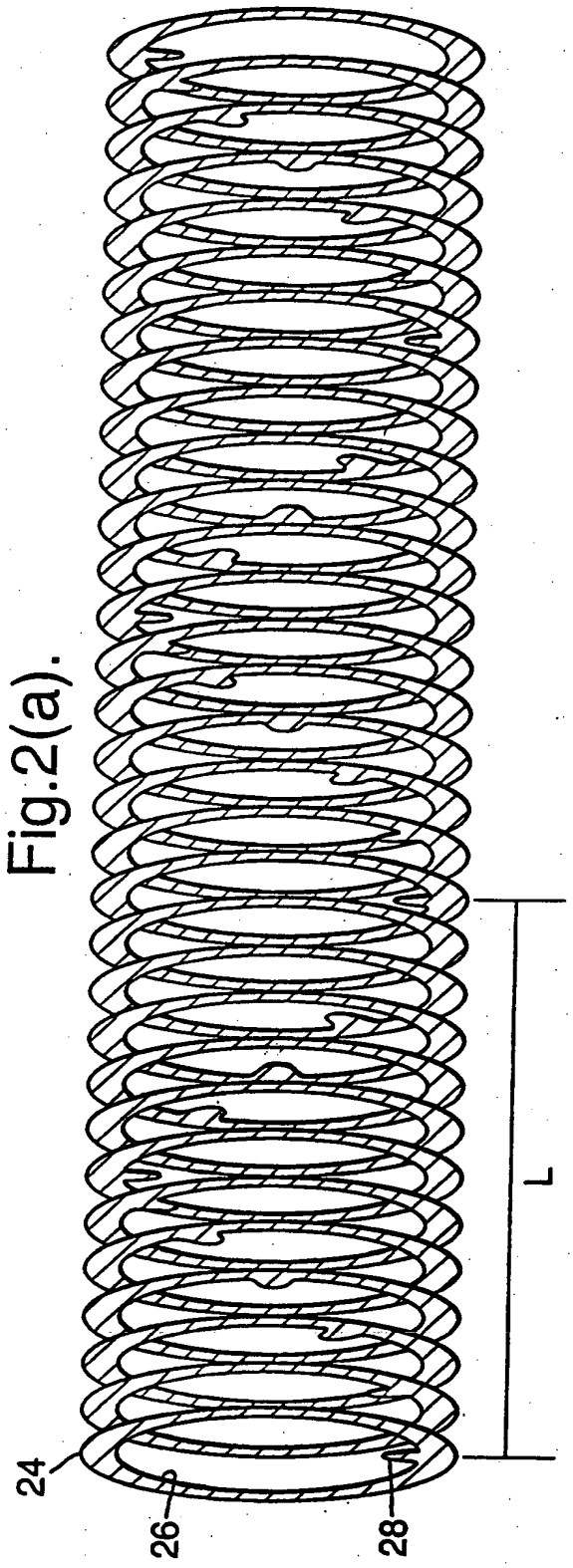

Fig.2(a).

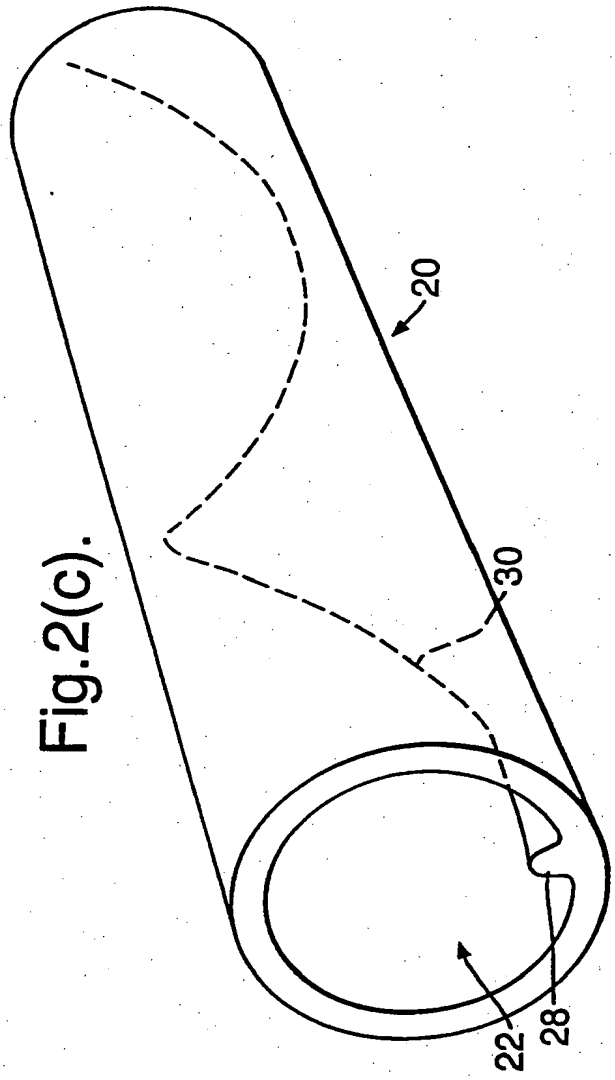

Fig.2(c).

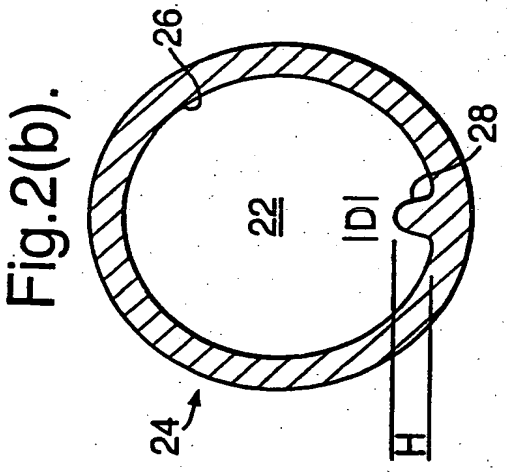

Fig.2(b).

Fig.4.

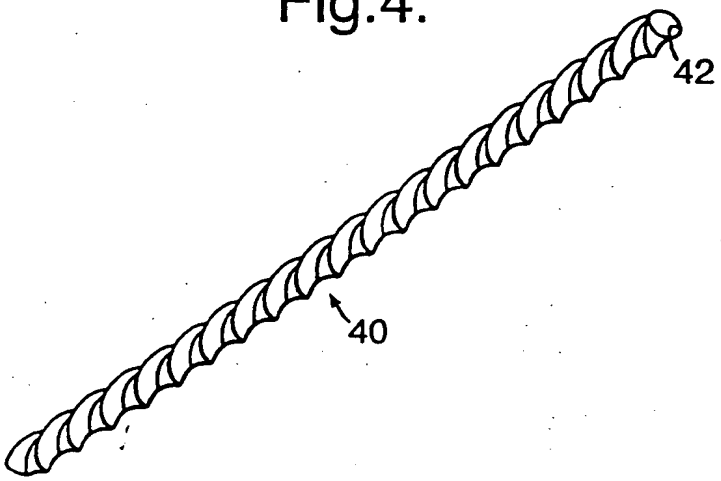
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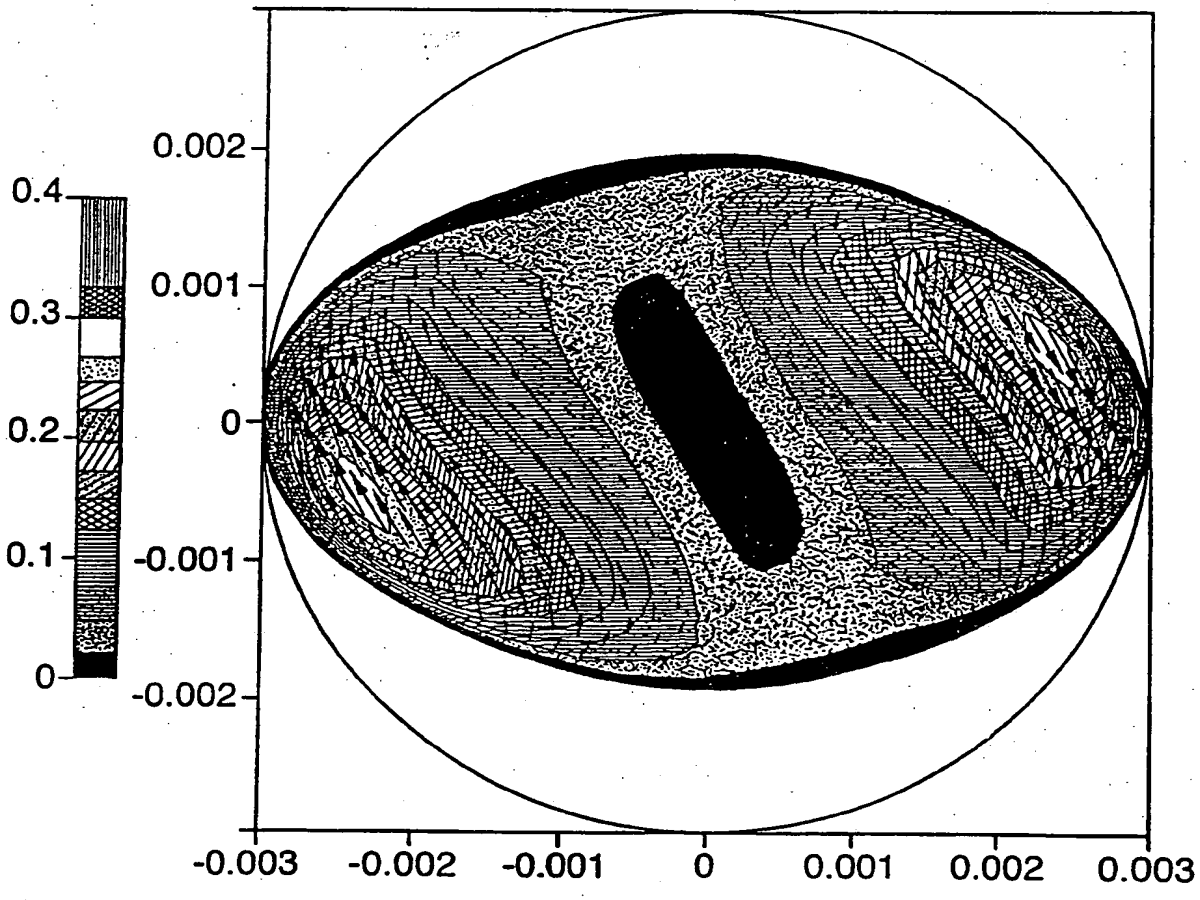
Fig.5.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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 00 30 1498

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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31-07-2000

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